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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,401	04/26/2000	Hiroyuki Yuyama	2000 0523A	1206

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/559,401

Applicant(s)

YUYAMA ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/19/04 has been entered.

Response to Amendment

2. In the amendment filed 3/19/04, the following has occurred: claim 10 has been amended. Now, claims 10-18 are presented for examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 10, 12, 14, 15, and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Bloom et al., U.S. Patent No. 6,070,761.

5. As per claim 10, Engleson teaches an apparatus for supporting injection mixing work, said apparatus comprising: a memory operable to store data for supporting injection mixing work, said memory being operable to store a patient predictability data file for storing patient predictability data including at least patient predictable information (see column 5, line 66 – column 6, line 2), an injection prescription data file for storing injection prescription data

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corresponding to the patient predictability data (see column 6, lines 2-6), and a combination related data file for storing combination related data corresponding to each injection of the injection prescription data (see column 6, lines 54-58); a display operable display the data stored in said memory (see column 2, lines 28-31); and a controller operable to determine a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, and to display the determined mixing order on said display (see column 8, line 66 – column 9, line 12 and Figure 9). Engleson does not explicitly teach determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection and that a mixing order is determined by the controller before the injections are dosed to the patient. Bloom teaches a system that supports delivery of intravenous drugs that includes determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection and that a mixing order is determined by the controller before the injections are dosed to the patient (see column 33, lines 45-59). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate these features into the system of Engleson. One of ordinary skill in the art would have been motivated to incorporate these features for the purpose of enhancing patient safety when prescribing injections of a plurality of different drugs.

6. As per claim 12, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson further teaches the combination related data file of said memory includes differentiation data for differentiating transfusion and solely administrated medicament, and wherein said controller is operable to classify the injection contained in the injection prescription data for a patient into transfusion or solely administrated medicament in accordance with the differentiation data and displays it on the display (see column 9, lines 40-52).

7. As per claim 14, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson further teaches the combination related data file of said memory stores attention information data related to each injection, and wherein the controller is operable to display an attention information in the attention information data on the display corresponding to each injection of the injection prescription data (see column 9, lines 63-67).
8. As per claim 15, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson further teaches a reader operable to read an identification code for identifying each injection, wherein said controller is operable to display a progress situation of mixing work on said display in accordance with the identification code read by the reader when conducting the mixing work of the injection (see column 7, lines 44-52).
9. As per claim 18, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson further teaches a reader operable to read a prescription identification code for identifying each injection prescription data, wherein said controller is operable to read the corresponding injection prescription data in accordance with the prescription identification code and displays it on the display (see column 7, lines 44-52).
10. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Bloom et al., U.S. Patent No. 6,070,761 and further in view of Merki et al., U.S. Patent No. 5,002,055.
11. As per claim 11, Engleson in view of Bloom teach the apparatus of claim 10 as described above. Engleson does not explicitly teach storing pH-values data for each injection and determining the mixing order of the injections in accordance with the pH-values data. Merki teaches storing pH-values data for injections, and wherein a controller decides a mixing order of the injections in accordance with the pH-values (see column 3, lines 52-63). It would have been

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obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate this feature into the system of Engleson. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety by regulating pH-values.

12. As per claim 16, Engleson in view of Bloom teach the apparatus of claim 15 as described above. Engleson further teaches the controller decides whether the injection is proper or not in accordance with the identification code of the injection read by the reader and if improper, displays it on the display (see column 7, lines 52-59). Engleson does not explicitly teach storing pH-values data for each injection and determining the mixing order of the injections in accordance with the pH-values data. Merki teaches storing pH-values data for injections, and wherein a controller decides a mixing order of the injections in accordance with the pH-values (see column 3, lines 52-63). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate this feature into the system of Engleson. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety by regulating pH-values.

13. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Bloom et al., U.S. Patent No. 6,070,761 and further in view of Mayaud, U.S. Patent No. 5,845,255.

14. As per claim 4, Engleson in view of Bloom teach the apparatus of claim 1 as described above. Engleson does not explicitly teach storing incompatibility data for showing whether or not two kinds of injections are incompatible and displaying the incompatibility on the display. Mayaud teaches storing incompatibility data showing whether or not a combination of two kinds

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of injections is incompatible, and wherein the controller decides whether or not a combination of two kinds of injections contained in injection prescription data for a patient is incompatible in accordance with the incompatibility data and displays it on a display (see column 31, lines 19-24). It would have been obvious to one of ordinary skill in the art of prescription management at the time of the invention to incorporate the incompatibility detection feature of Mayaud into the invention of Engleson. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety when prescribing injections of a plurality of different drugs.

15. As per claim 8, Engleson in view of Bloom and Mayaud teach the system of claim 4 as describe above. Engleson does not explicitly teach inputting new incompatibility data and storing it in the combination related data of the memory. Mayaud teach inputting new incompatibility data in addition to stored incompatibility data and storing it in a combination related data in memory (see column 31, lines 33-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to make add this feature to the system of Engleson for the reasons given above with respect to claim 4.

Response to Arguments


16. In the remarks filed 3/19/04, Applicants argue in substance that none of the applied prior art teach that a mixing order is determined before the injections are dosed to a patient. In response to Applicant's arguments, the Examiner respectfully submits that the teachings of Bloom have now been relied upon for these limitations. Therefore, these arguments are moot in view of the new grounds of rejection.

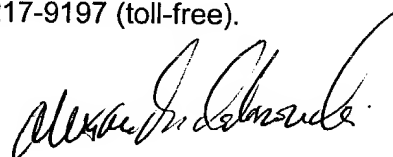
Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


CLG
7/6/04


ALEXANDER KALINOWSKI
PRIMARY EXAMINER